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Toxic Substances Control Act (TSCA) Report to Congress for Fiscal Year 1981

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Toxic Substances Control Act (TSCA) Report to Congress for Fiscal Year 1981

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This fourth annual report to Congress summarizes progress made during FY 1981 by the Environmental Protection Agency (EPA) in implementing the Toxic Substances Control Act (Public Law 94-469, 94th Congress). It fulfills the congressional reporting requirements of sections 9 (D), 28 (c), and 30 of the Act.

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TSCA REPORT TO CONGRESS

FOR FISCAL YEAR 1981

January, 1982

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OFFICE OF TOXIC SUBSTANCES
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Note: This report covers activities in Fiscal Year 1981

INTRODUCTION

This fourth annual report to Congress summarizes progress made during Fiscal Year 1981 by the Environmental Protection Agency (EPA) in implementing the Toxic Substances Control Act (Public Law 94-469, 94th Congress). It fulfills the congressional reporting requirements of sections 9(d), 28(c), and 30 of the Act.

Implementing the Toxic Substances Control Act (TSCA) is the responsibility of the EPA Office of Toxic Substances. Overall responsibility for the TSCA program continues to be that of the Assistant Administrator for Pesticides and Toxic Substances, a position that reports directly to the Administrator.

TSCA took effect on January 1, 1977. Programs now exist under the Act to gather available information about the toxicity of particular chemicals and the extent to which people and the environment are exposed to them, to bring about industry testing where existing data are inadequate, to assess whether particular chemicals cause unreasonable risks to humans or the environment, and to institute appropriate control actions after carefully weighing the risk against the benefits provided by particular chemicals to the nation's economic and social well-being.

To help ensure informed decisionmaking by the government, TSCA gives EPA authority to gather basic information on chemical risks from the manufacturers and processors of such substances. The law also enables EPA to require companies to test chemicals for toxic effects and stipulates that companies are to submit to EPA certain specified information on all new chemicals before they are manufactured. To prevent unreasonable risks, EPA under TSCA may select from a broad range of control actions, from requiring hazard-warning labels to outright bans on the manufacture or use of especially hazardous substances. TSCA authorizes EPA to regulate unreasonable risks at any stage in a chemical's life-cycle: in manufacturing, processing, distribution in commerce, use, and/or disposal.

In assigning these authorities to EPA in order to implement TSCA, Congress intended that prudence be exercised. EPA's actions under TSCA acknowledge the significant role that the chemical industry plays in the economy of the United States: in 1980, for example, the industry's annual sales approached $162 billion and generated an annual trade surplus of about $12 billion; the production of chemicals and allied products accounted for roughly 5 percent of the Gross National Product; and the industry employed about 1.1 million people.

Research done by the Agency shows that chemical production is not evenly distributed among the 11,000 establishments involved in the manufacture and processing of chemicals. The five largest companies in terms of chemical sales, account for 22 percent of industry sales, and the fifty largest account for more than 60 percent. However, most chemical firms are small--53 percent employ fewer than 100 people.

In creating TSCA Congress recognized that too often in the past the hazards of particular chemicals were discerned only after extensive harm had occurred to human health and the environment. Asbestos is a well-known example of such a hazard. In other instances adverse effects are suspected but have not been proven to the extent necessary for regulatory decisionmaking. The thrust of TSCA is to make it the industry's responsibility to develop missing data where there is a bona fide indication of potential risk.

The Agency's basic approach in implementing TSCA has been to use the Act's various provisions to stimulate better and more timely industry assessments of chemical risks. This approach should lead to more rapid and cost-effective achievement of the Agency's main statutory goals than would a chemical-by-chemical regulatory approach. In a number of instances, for example, when the TSCA program has identified a suspect chemical, the industry has voluntarily undertaken risk-reduction measures such as improving in-plant emission controls or has instituted toxicity testing.

Implementation of TSCA, by Section of the Law, FY 1981

Section of Law	Description	Action	Date
4(a)	Testing for health and environmental effects: nitrobenzene	Proposed rule	6/5/81 (46 FR 30300)
4(a)	Testing for health and environmental effects: dichloromethane	Proposed rule	6/5/81 (46 FR 30300)
4(a)	Testing for health and environmental effects: 1,1,1-trichloroethane	Proposed rule	6/5/81 (46 FR 30300)
4(b)	Test standards for physical, chemical, and environmental persistence characteristics	Proposed rule	11/21/80 (45 FR 77332)
4(b)	Good laboratory practices standards for physical, chemical, and environmental persistence characteristics and for ecological effects testing	Proposed rule	11/21/80 (45 FR 77353)
5(a)	Revised interim policy, premanufacture notification	Interim policy	11/7/80 (45 FR 74378)
5(a)	Draft regulatory analysis; proposed economic impact analysis	Proposed rule	11/13/80 (45 FR 74945)
5(a)	Chemical-specific SNUR	Proposed rule	11/26/80 (45 FR 78970)
6(a)	CFC production limitations	Advance notice of proposed rulemaking (ANPR)	10/7/80 (45 FR 66726)
6(e)	PCB Manufacturing, processing, distribution in commerce, and use prohibitions; proposed restrictions on use of PCBs at agricultural pesticide and fertilizer facilities; abeyance of proposed rule amendment	Proposed rule amendment; notice of abeyance	5/6/81 (46 FR 25411)

6(e)	Use of PCBs in electrical equipment	Rule-related court order and enforcement notice	3/10/81 (46 FR 16069)
6(e)	Use of PCBs in electrical equipment	Advance notice of proposed rulemaking (ANPR)	3/10/81 (46 FR 16096)
6(e)	Use of PCBs in electrical equipment	Rule-related notice	5/20/81 (46 FR 27614)
6(e)	PCBs: Court order regarding PCBs in concentrations below 50 ppm	Rule-related notice	5/20/81 (46 FR 27615)
6(e)	PCBs: Manufacturing of PCBs in concentrations below 50 ppm; possible exclusion from manufacturing prohibition	Advance notice of proposed rulemaking (ANPR)	5/20/81 (46 FR 27617)
6(e)	Manufacturing, processing, distribution in commerce, and use prohibitions; PCBs in concentrations below 50 ppm	Advance notice of proposed rulemaking (ANPR)	5/20/81 (46 FR 27619)
12(b)	Export notifications to foreign governments	Final rule	12/16/80 (45 FR 82844)
13	Customs entry policy	Proposed policy	12/1/80 (45 FR 79726)
21	PCBs: Denial of citizens' petition	Proposed rule-related notice	12/4/80 (45 FR 80320)

TSCA SECTION 4: TESTING OF CHEMICAL SUBSTANCES AND MIXTURES

Section 4 of TSCA gives EPA authority to require manufacturers or processors of chemicals to test designated substances for toxic effects. EPA exercises this authority only when it can make certain statutory findings about the substance involved. These required findings are that a chemical may present an unreasonable risk; that there are insufficient data available with which to perform a reasoned risk assessment; and that testing is necessary to provide such data. A test rule also may be based on an Agency finding of substantial production and exposure to humans or the environment, in addition to findings of insufficient data and the need for testing.

Testing methodology requirements: Testing required by rule is to be performed according to prescribed standards developed by EPA in consultation with other government agencies, nongovernment scientific experts, industry, foreign governments, and the general public. The test standards are to prescribe the health and environmental effects, as well as information relating to toxicity and other characteristics, for which test data are to be developed. In addition, to the extent necessary to assure reliable and adequate data, EPA is authorized to prescribe the test methodology to be employed and other requirements. Such requirements will assure uniformly reliable and consistent results from a variety of domestic and foreign sources of data.

Generic test standards: The Agency had previously indicated its intention to impose relatively rigid generic testing methodology requirements that were to be incorporated in rules for testing individual chemicals. Under this approach, EPA published proposals for health effects testing on May 9, 1979 (44 FR 27334), and on July 26, 1979 (44 FR 44054), and proposals for physical, chemical, and environmental persistence characteristics testing on November 21, 1980 (45 FR 77332). Since publishing these proposals, Agency staff have developed additional test methodology guidelines for mutagenicity, neurotoxicity, ecological effects, and physical, chemical, and environmental persistence characteristics.

Significant effort has been made to harmonize TSCA testing methodologies with the protocols of other U.S. Government agencies in the Interagency Regulatory Liaison Group (IRLG)* and with the International Testing Standards developed by the 24

*The IRLG member agencies were EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Food Safety Quality Service (FSQS) of the Department of Agriculture. The four-year interagency agreement establishing the IRLG expired on September 26, 1981.

member nations of the Organization for Economic Cooperation and Development (OECD).

New approach: Generic methodology guidelines. EPA has recently decided to issue test methodologies as informal guidelines rather than as generic methodology requirements. These guidelines will be one of several sources from which the Agency may choose to adopt methodological requirements for testing individual chemicals on a rule-by-rule basis. This approach affords the Agency the flexibility to modify the requirements to fit different chemicals. In so doing it allows the Agency to determine the most cost-effective methodology and gives testing laboratories an opportunity to make full use of their scientific judgment in suggesting appropriate methodologies. The test methodology guidelines also would serve as guidance for voluntary testing conducted by the chemical industry.

Good laboratory practices: In addition to test methodologies, the Agency also has proposed Good Laboratory Practice (GLP) standards for health effects testing (44 FR 27362) and for physical, chemical, persistence, and ecological effects testing (45 FR 77353). The final GLP standards, which delineate proper procedures for conducting laboratory testing, will be promulgated as regulatory requirements, as originally proposed. After a review of the evidence compiled by the Food and Drug Administration (FDA) and EPA in their laboratory inspection/ auditing programs, EPA determined that implementation of the GLP protocols as regulations is justified to provide increased quality and integrity in the test data that will be submitted to the Agency under TSCA.

Proposed testing rules: On June 5, 1981, EPA proposed the second set of TSCA testing rules under authority of Section 4(a) of the Act. The proposed rules would require testing for the health and environmental effects of nitrobenzene, dichloromethane, and 1,1,1-trichloroethane, all of which had been recommended for priority testing by the Interagency Testing Committee (ITC).*

Nitrobenzene: The proposed nitrobenzene rule would require testing for teratogencicity and reproductive effects based on the finding that nitrobenzene may present an unreasonable risk of injury to human health. The proposed rule would also require testing for certain environmental effects and for adsorption to

*The ITC was created by TSCA to recommend chemicals to EPA for priority consideration for test rules under Section 4(a) of the Act. Its member agencies are EPA, the Occupational Safety and Health Administration (OSHA), the Council on Environmental Quality (CEQ), the National Institute for Occupational Safety and Health (NIOSH), the National Cancer Institute (NCI), the National Science Foundation (NSF), the National Institute of Environmental Health Sciences (NIEHS), and the Department of Commerce.

soils. The basis for proposing environmental testing is the finding that nitrobenzene is produced in substantial quantities and is released into the environment in substantial amounts. EPA also found that currently there are insufficient data available with which it can evaluate the environmental effects of that release and the listed health effects of human exposure ascribed to the substance.

Dichloromethane: The proposed dichloromethane rule would require testing for certain health effects and certain environmental effects for which there currently are insufficient data available. The proposal is based on the finding that dichloromethane is produced in substantial quantities, that there is substantial human exposure to this substance, and that there is substantial release of this substance to the environment.

1,1,1-Trichloroethane: The proposed 1,1,1-trichloroethane rule would require testing for teratogencity and for certain environmental effects for which there are currently insufficient data available. The proposal is based on the finding that 1,1,1-trichloroethane is produced in substantial quantities, that substantial numbers of persons are exposed to this substance, and that there is substantial release of this substance to the environment.

Testing Costs: Because the TSCA testing rules have been proposed for public comment and have not yet taken effect, no costs for testing chemicals were actually borne by industry during fiscal year 1981.

Testing rule schedule: The Interagency Testing Committee (ITC) has submitted a total of eight priority lists to EPA; 26 individual chemicals and 19 chemical groups or categories have been identified by the Committee for test rule consideration. In 1979 the Natural Resources Defense Council (NRDC) challenged EPA's responses to the first two sets of recommendations by the ITC. On February 4, 1980, the U.S. District Court announced its decision in NRDC's favor and instructed EPA to establish a schedule for responding to the backlog of ITC recommendations. The Court issued a final order in January 1981. Under the schedule EPA is required to respond to a total of 11 ITC recommendations during calendar year 1981.

In response to this lawsuit and to EPA's own concerns about the Section 4 program, the Agency reevaluated and substantially modified its approach to evaluating ITC recommendations and developing Section 4 test rules. In 1981 this contributed to more efficient and timely test rule development. As part of this new procedure, EPA held "scoping" conferences in March and July 1981 on the subject of the ITC's seventh and eighth sets of recommendations. These conferences provide an early opportunity for input from the industry, academia, and others in order to sharpen the Agency's focus on the issues it needs to consider.

TSCA SECTION 5: NOTIFICATION AND REVIEW OF NEW CHEMICALS

Premanufacture notification: Section 5 of TSCA requires that any person who intends to manufacture (or import) a new chemical substance for commercial purposes in the United States must submit a notice to EPA at least 90 days before commencing manufacture or import of the substance. A "new chemical substance" is any chemical substance that does not appear in the TSCA Chemical Substances Inventory. The notice must contain information specified in Section 5(d), including any information derived from testing for health and environmental effects.

Under Section 5(a)(2), the Administrator is authorized to issue a Significant New Use Rule (SNUR) that requires notification through the PMN process by anyone who proposes to manufacture or process a subject chemical for certain "new" uses defined in the rule.

A person who wants to manufacture a new chemical substance for test marketing purposes can submit a test market exemption application (TMEA) under Section 5(h)(1) of the Act. The Agency must either grant or deny the TMEA within 45 days and publish notice of this action in the Federal Register. The submitter must show that the manufacturing, processing, distribution in commerce, use, or disposal of the TMEA substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment under the test marketing conditions specified in the application.

Premanufacture Notification (PMN) rules: On January 10, 1979, EPA published in the Federal Register proposed rules and notice forms for the PMN program. In response to comments, the Agency reproposed portions of the rules and a revised form on October 16, 1979. The reproposal designated the rules as "major" rules under Executive Order 12044 and announced that the appropriate regulatory and economic analyses would be conducted and published for comment. The methodology for the economic impact analysis was published in the Federal Register on June 10, 1980, and the regulatory and economic impact analyses were published for comment on November 13, 1980. A public meeting was held on April 8, 1981, the close of the 120-day comment period. The two analyses are being revised to reflect the comments received. In addition to the October 1979 reproposal, the Agency published a clarification of the definition of the term "importer" in the Federal Register on September 23, 1980. In August 1980 the Agency proposed that processors of certain exempt substances submit notices prior to processing for a nonexempt purpose. Until final rules are promulgated, the new-chemical review program will operate under the Interim Guidance published in the Federal Register on May 15, 1979, and November 7, 1980.

Under Section 5(h)(4) EPA may exempt from any PMN requirements by rule new chemical substances for which the manufacturing, processing, distribution in commerce, use, or disposal will not present an unreasonable risk of injury to health or the environment. The Agency is working on several exemptions to the premanufacture notice requirements in response to applications filed by industry. The first application for an exemption under Section 5(h)(4) of the Act was filed by Polaroid Corporation in April 1980. Additional petitions for exemptions were filed by the Chemical Manufacturers Association (CMA) in May 1981, the Synthetic Organic Chemical Manufacturers Association (SOCMA) in June 1981, the Dyes Environmental and Toxicology Organization (DETO) in July 1981, and Ashland Chemical Company in August 1981. Late in 1981 EPA proposed a rule to exempt new chemicals used in or for instant photographic film articles from premanufacture notice requirements. The proposal is in response to the Polaroid petition.

New-chemical review process: Following the receipt of a notice by the Agency, review of the new chemical substance is carried out in three phases: initial review, detailed review, and an action phase. The initial review identifies concerns that may be raised for health and environmental effects and environmental release of the substance. A substance that may pose an unreasonable risk and that requires further study is the focus of a detailed review. The Agency conducts a detailed review of all information that it can reasonably obtain regarding the concerns about the substance. If sufficient data are not available on the specific new chemical, information on closely related existing chemicals is used. The detailed review identifies data gaps and recommends further testing that may be appropriate. For good cause, TSCA authorizes in Section 5(c) an extension of the 90-day review period for up to an additional 90 days, to permit completion of the detailed assessment. In FY 81, the review period was extended for three such cases.

When concerns raised are substantiated by a detailed review or when insufficient information is available to make a reasoned evaluation and there may be an unreasonable risk of injury to health or the environment or there may be significant exposure, the Agency can take action to control the PMN substance. EPA can propose an order under Section 5(e) or 5(f); however, other alternatives are open to the Agency. As discussed earlier, the Agency may, for example, promulgate a significant New Use Rule under Section 5(a)(2) for the subject new chemical for certain "new" uses defined in the rule. Or EPA may issue a follow-up reporting requirement under Section 8(a) to ensure notification should a manufacturer propose to produce the chemical in excess of a given production volume or for specified uses. In many cases the Agency and the submitter can work together to develop voluntary controls for reducing exposure that would mitigate Agency concerns.

Section 5(e) and 5(f) orders: A Section 5(e) order is issued to limit or to ban the manufacture, processing, distribution in commerce, use, or disposal of a new chemical substance pending development of additional information. In 1981 work was begun on two Section 5(e) orders; both PMN substances were direct type blue fabric dye chemicals. The PMNs for these two substances were withdrawn by the submitters in anticipation of the 5(e) orders being served.

A Section 5(f) order is issued to prohibit the manufacture, processing, or distribution in commerce of a new chemical substance that has been shown to present an unreasonable risk; under Section 5(f) EPA may also issue a proposed rule, effective immediately, to limit the manufacture, processing, or distribution in commerce of the substance. No Agency action under these authorities in Section 5(f) was required in 1981.

Test market exemption applications (TMEAs): In an application for a test marketing exemption the submitter must show that there will be no unreasonable risk of injury to health or the environment caused by test marketing the substance. Based on information provided in the submitter's application, the Agency must either grant or deny the exemption within the 45-day time period prescribed by the Act. In FY 1981 the Agency received 40 TMEAs.

Section 5 PMN Review Summary, October 1, 1980 - September 30, 1981

Description	Total
Total valid PMNs submitted	581
PMNs for which a 5(c) extension was issued	3
PMNs withdrawn	2
5(e) orders initiated	2
5(e) orders issued	0
Total valid TMEAs	40
TMEAs granted	38
TMEAs denied	2
TMEAs withdrawn	0

TSCA Section 6: REGULATION OF HAZARDOUS CHEMICAL SUBSTANCES AND MIXTURES

Chemical control: Under Section 6 of TSCA, EPA has the authority to prohibit or limit the manufacture, processing, distribution in commerce, use, and/or disposal of chemicals that are found to pose an unreasonable risk to human health or the environment. A number of possible control options are available, ranging from total prohibition to labeling. In 1981 EPA undertook activities intended to lead to control actions against polychlorinated biphenyls (PCBs), 2,3,7,8-tetrachlorodibenzo-para-dioxin (TCDD), asbestos, and chlorofluorocarbons (CFCs).

Polychlorinated Biphenyls (PCBs)

Final control action, PCBs: In TSCA Congress singled out PCBs for both immediate regulation and phased withdrawal from the market; the only exceptions to this occur if EPA grants authorizations or exemptions for specific activities. PCBs are of concern because tests on laboratory animals show that PCBs cause, among other effects, reproductive failures, gastric disorders, skin lesions, and tumors. Moreover, PCBs persist when released into the environment and tend to accumulate in tissues of living organisms. This means that, as PCBs move up in the food chain toward humans, their concentration, and thus their potential for harm, increases.

Control of PCBs was initiated in February 1978, when EPA issued final PCB marking and disposal rules. Fifteen months later, the Agency promulgated a final rule banning the manufacture, processing, distribution, and non-totally enclosed uses of PCBs.

In July 1979 the Environmental Defense Fund (EDF) filed a suit against EPA challenging aspects of the Agency's final PCB ban rule. On October 30, 1980, the Court ruled in favor of EDF on two of the three major issues in the case and remanded certain portions of the rule to EPA for further proceedings.

In FY 1981 EPA was ordered by the Court to develop new regulations governing the use of PCBs in electrical equipment and to formulate a plan for dealing with PCBs in low concentrations. EPA has issued Advance Notices of Proposed Rulemaking (ANPRs) on three subjects: (1) the use of PCBs in electrical equipment, (2) the exclusion from regulation of PCBs manufactured under circumstances that involve little or no risk, and (3) the manufacture, processing, distribution in commerce, and use of PCBs in low concentrations. The Edison Electric Institute, the Chemical Manufacturers Association, and the Dry Color Manufacturers Association are

performing studies on PCBs. These studies and the public comments on the ANPRS will form the factual record EPA will use to accomplish its Court-ordered tasks.

On May 9, 1980, because of the serious potential consequences to public health from food accidentally contaminated with PCBs, the EPA, the Department of Agriculture, and the Food and Drug Administration* simultaneously proposed rules banning the use of PCB-containing equipment from food- and feed-processing plants and storage facilities; federally inspected meat, poultry, and egg product establishments; and agricultural chemical facilities where pesticides and fertilizers are manufactured or stored.

EPA's proposal would have amended the final PCB regulation under Section 6 by prohibiting the use of such items as PCB-containing capacitors and transformers in all facilities manufacturing, processing, or storing fertilizers or agricultural pesticides. On May 6, 1981, that proposed rule was placed in abeyance, pending the outcome of new rulemaking that will be conducted to resolve the EDF case.

TCDD

Final control action, TCDD: TCDD (which refers to 2,3,7,8-tetrachlorodibenzo-para-dioxin, one of several possible isomers of polychlorinated dioxins) is a highly toxic chemical found as an unintended contaminant in other substances, particularly the phenoxy herbicide 2,4,5-T (2,4,5-trichlorophenoxy acetic acid). TCDD, familiar as dioxin, is a known carcinogen in laboratory animals that also produces a wide range of other adverse health effects (chloracne and organ dysfunction, for example). Some studies show a relationship between exposure to dioxin and the occurrence of these latter effects in some human populations.

In May 1980 EPA promulgated a rule under Section 6(a)(6) of TSCA prohibiting Vertac, Inc., from disposing of certain TCDD-contaminated wastes produced before May 1980 at its Jacksonville, Arkansas, facility. Those wastes must remain stored at the site. The rule allows Vertac to dispose of wastes that were produced after May 1980, which are less contaminated with TCDD, in landfills approved for PCB disposal. In September 1981 EPA's Region VI office determined that a landfill in Calcasieu,

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* These agencies, through a cooperative effort headed by the TSCA Industry Assistance Office, disseminated about 20,000 hazard-alert pamphlets to food and feed establishments to promote swift precautionary measures.

Louisiana, did not meet PCB disposal requirements, thereby preventing Vertac from disposing of its post-May 1980 wastes there.

The rule also requires anyone who intends to dispose of wastes resulting from the production of 2,4,5-trichlorophenol or from its pesticide derivatives, to notify EPA at least 60 days before disposal so that the Agency can determine the adequacy of the proposed disposal method. These products generally cover most substances contaminated with TCDD. EPA is considering whether to replace the storage and notification provisions of the rule with specific requirements for the long-term disposal of all TCDD-contaminated wastes and plans to publish an ANPR late in 1981 to solicit information on currently used disposal methods. The ANPR will also solicit input from Vertac, Inc., that describes Vertac's preferred method for disposing of its pre-May 1980 wastes.

The Agency also is evaluating the combustion emissions, including TCDD, from several industries. In FY 1981 results of tests at two waste combustion facilities revealed and quantified TCDD in stack emissions from one of the plants. Four coal-burning power plants also were sampled. Analytical results from these are expected early in 1982.

Asbestos

Proposed control action, asbestos in schools: Scientific evidence points to asbestos fibers as a cause of lung damage and a rare mesothelioma type of lung cancer in humans. For many years asbestos was widely used to insulate buildings, in industrial and commercial products, and in other materials. The practice of spraying asbestos in buildings was virtually halted in 1973; by that time, however, many schools and other buildings had already been constructed with asbestos-containing materials. The EPA program to reduce asbestos hazards in schools began in March 1979 with a nationwide voluntary technical assistance program to help States and local school districts identify friable (crumbling) asbestos materials in schools and to take corrective action where necessary. Because thousands of schools did not participate in this program, EPA proposed a rule in September 1980 that would require all public and private primary and secondary schools to identify this type of asbestos and notify school employees and other appropriate people of the results of such inspections.

Since 1979 and concurrently with rulemaking activities, EPA has sponsored an active technical assistance program to States and to local school districts. A series of asbestos documents has

been published that provides guidance to school districts attempting to comply with the proposed identification and notification rule. The documents deal with a variety of issues, including inspection, assessment, and sampling and analysis of asbestos-containing materials. In addition, technical assistance is available through a toll-free telephone number. Finally, EPA has sponsored an on-going quality assurance program to address the problems associated with laboratory analysis of asbestos-containing materials.

Rulemaking proceeding, asbestos use: As part of a continuing investigation of the hazards associated with exposure to asbestos, EPA will complete in late 1981 a contract study to identify and evaluate substitutes for asbestos. Although there is no known material that can replace every asbestos use, substitutes are available for many specific uses. EPA plans to use this information to assess the magnitude of asbestos exposure from commercial and industrial uses and, if necessary, to design measures to reduce those exposures. Action under TSCA is being coordinated with EPA actions under other statutes and with the actions of other Federal agencies.

Chlorofluorocarbons (CFCs)

Rulemaking proceeding, CFCs: In response to concerns raised by the findings of the 1979 National Academy of Sciences' assessment of the CFC/ozone depletion issue, EPA issued an Advance Notice of Proposed Rulemaking (ANPR) in October 1980 to gather information about the validity of the ozone depletion theory, the appropriateness of restricting the use of CFCs, and possible alternative courses of action for the Agency. The Agency received more than 2,000 comments. A preliminary analysis of those comments led the Agency to conclude that many of the issues raised deserve additional study.

EPA has initiated further analysis of the CFC issue. Staff are working closely with experts in and out of government studying the unresolved scientific questions and economic implications of CFC emission reductions. Scientists at other Federal agencies, as well as in academia and industry, are evaluating the potential effects of CFCs, other halocarbons, carbon dioxide, and nitrogen oxide on the stratosphere. Laboratory measurements, atmospheric observations, and theoretic studies (modeling) are being used. Current central estimates of various models indicate that present CFC-11 and CFC-12 emissions, if continued, may result in 5 to 10 percent ozone depletion; due to uncertainties in stratospheric chemistry and physics, however, the estimate may be in error by a factor of 2 in either direction (from one half to double the central estimates). Contractors to EPA are performing further economic and technical analysis of various methods for reducing CFC emissions in nonaerosol applications.

EPA contracted with the National Academy of Sciences (NAS) for an assessment of the most recent scientific information regarding stratospheric ozone changes and the resultant effects. The Agency anticipates receiving the NAS report by March 1982.

EPA has been involved in international cooperation on the CFC issue in scientific research, monitoring efforts, and assessments, such as the work of the United Nations Environmental Program's Coordinating Committee on the Ozone Layer (CCOL), the World Meteorological Organization, various other international scientific organizations, and several bilateral research projects. In addition, the United States is a member of the 24-nation Organization for Economic Cooperation and Development (OECD), which has been a forum for exchanging information on science, technology, economics, and regulatory aspects of CFCs. In view of the global implications of the CFC issue, it is important that the Agency continue to work with other countries, and that EPA consider domestic CFC efforts in the context of the work of the international community.

In addition, EPA staff are continuing to process requests for exemptions to the 1978 rule, which banned nonessential aerosol uses of CFCs. Exemption requests are evaluated on the basis of the availability of substitutes, the economic significance of the product, the environmental and health impacts of the aerosol product and its substitutes, and the effect on the quality of life if the product or a reasonable substitute were unavailable.

In 1981 the Agency proposed to grant exemption requests for the aerosol use of CFCs as a propellant for substances used to lubricate pharmaceutical rotary press punches and as the propellant for spinerette-release agents used in the production of man-made fibers. The Agency also granted a temporary exemption for the use of CFCs in automatic pesticide dispensing systems for long-term storage of flue-cured tobacco, pending a review of a request for a permanent exemption. EPA denied two applications for exemptions: for CFC used in spray adhesives and in fog machines used in theatrical productions. Four exemption requests are now under investigation by the Agency.

TSCA SECTION 9(d): RELATIONSHIP OF TSCA TO OTHER FEDERAL LAWS

Coordination with other chemical programs: Section 9(d) of TSCA requires coordination and consultation with other Federal programs involved in toxic chemical regulation to achieve maximum effectiveness of TSCA and minimum duplication of effort and purpose.

Toxic Substances Priorities Committee (TSPC):* The TSPC is an EPA-wide Committee of office directors charged with resolving those toxic substances problems that cannot be dealt with by a single program office. The Committee is responsible for promoting consistency and minimizing duplication in Agency activities, ranging from identifying major toxic substances problems to performing risk assessments and developing regulations. The TSPC has focused its attention on developing an Agencywide risk assessment of toluene and an Agencywide strategy for assessing and controlling, where appropriate, six chlorinated organic chemicals used as metal degreasing solvents. The solvents strategy has involved more than one major analysis, including overall exposures, health and ecological hazards, risk assessments, chemical substitutes, cost-effectiveness of past controls, regulatory effectiveness, and potential control options. The final solvents strategy will be completed in FY 1982 and will be evaluated as a model for future Agencywide chemical/industry work groups.

Interagency Regulatory Liaison Group (IRLG):** The IRLG, which included EPA, the Consumer Product Safety Commission (CPSC), the Food and Drug Administration (FDA), the Occupational Safety and Health Administration (OSHA), and the Food Safety Quality Service (FSQS) of the Department of Agriculture, sought to integrate and coordinate information and activities on a governmentwide basis, in order to avoid duplication of effort and promote cost-effective chemical control programs. Among its activities in FY 81, the IRLG established a task group on DEHP (diethylhexyl phthalate); sponsored with the National Toxicology Program a three-day symposium on phthalates; and worked with the Departments of Energy and Housing and Urban Development to develop a multimedia risk assessment of formaldehyde. EPA also coordinated the development of PCB regulations with the FDA and the FSQS.

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*The role of the TSPC is being re-examined as part of an Agency-wide evaluation of interprogram committees and may, therefore, change in FY 1982.

**The four-year interagency agreement establishing the IRLG expired on September 26, 1981. The Agency is now represented at the Regulatory Work Group on Science and Technology chaired by the White House Office of Science and Technology.

Relationship of TSCA to international activities: The EPA has been a full and regular partner in extensive international consultations and negotiations in the Chemicals Program of the 24-nation Organization for Economic Cooperation and Development (OECD) during the development of the Agency's chemical testing and other requirements under TSCA. The Agency places a high priority on these activities because of benefits both for international chemical trade and for more effective health and environmental protection.

U.S. experts, along with those of other OECD member states, have worked since 1977 to develop chemical testing guidelines and good laboratory practices, as well as a set of data that should be developed for new chemicals prior to marketing.

The OECD Council took formal action on parts of the Chemicals Program work in May 1981, adopting a Decision on the Principle of Mutual Acceptance of Data, which incorporates the Test Guidelines and Good Laboratory Practices.

EPA is also involved in a number of other cooperative international forums aimed at exchanging knowledge and building mutual understanding on chemical safety issues. Among these are the United Nations Environment Program's (UNEP) International Registry of Potentially Toxic Chemicals (IRPTC), the World Health Organization's (WHO) International Program on Chemical Safety, and the WHO Project on Assessment of Human Exposure to Pollutants through Biological Monitoring.

TSCA SECTION 16: ENFORCEMENT

Under Section 16 of TSCA, EPA may levy either civil or criminal penalties for a violation of several sections of the Act. Specific enforcement strategies for implementing regulations have been developed by the Agency. These strategies identify and rank possible violations of a particular regulation, identify the tools available for compliance monitoring and how they will be used, provide a formula for determining application of inspection resources, and establish policy for determining civil penalties under the regulation.

Violations of Section 6: In FY 1981 all enforcement actions under Section 16 involved alleged violations of the Section 6 PCB rules. EPA conducted 1,000 PCB compliance monitoring inspections and filed a total of 115 civil complaints during the fiscal year; 66 cases were completed, and $537,895 in civil penalties was assessed. Figures for each Region appear in the table.

The largest single penalty, $61,000, was assessed against Consolidated Edison Company of Long Island City, New York. In March 1980, 3,400 gallons of PCB-contaminated oil spilled from the facility into the East River. Other violations at the facility included improper storage and marking of large quantities of PCBs and failure to maintain complete records.

Criminal cases must be filed on EPA's behalf in Federal court by the Department of Justice. A major criminal action was initiated under Section 16(b) of TSCA against Wes-Con, Inc., a waste disposal company in Boise, Idaho, for alleged improper disposal of PCBs. On July 30, 1980, a grand jury indictment was issued against Wes-Con charging the company with emptying PCB wastes into its own landfill and then concealing that activity by generating false and misleading disposal records. Subsequently, a jury found the company guilty of improper disposal of PCBs, and on January 16, 1981, the company was fined $3,500.

On May 22, 1981, a Federal jury in North Carolina found Robert E. Ward, of the Ward Transformer Company, guilty of aiding in the illegal dumping of thousands of gallons of transformer oil contaminated with PCB on roadsides in that State in the summer of 1978. In June the Court sentenced Ward to 2 ½ years in prison and levied a fine of $200,000. Another person involved in the case was sentenced to 1 ½ years in prison and two others were placed on 5 years' probation.

Compliance with other TSCA requirements: EPA has also taken action to enforce compliance with other TSCA requirements, although so far there has not been a need to invoke Section 16. The Agency conducted 46 inspections to monitor compliance with the interagency ban on nonessential aerosol uses of CFCs and two inspections to determine compliance with import requirements under Section 13. Also in FY 1981 the Agency inspected five

firms that had failed to meet the deadline for reporting identities of existing chemicals as required under Section 8(b) of TSCA. The inspections were held to ensure that the substances reported late to the Agency were not in fact new chemicals subject to the PMN requirements of Section 5. There were 10 inspections and compliance monitoring reviews of facilities subject to Section 5 requirements.

During FY 1981 strategies were developed for the enforcement of Section 8 PPB/TRIS and Section 6 dioxin rules, as well as for the PCB interim measures program. Preliminary enforcement response policies were developed for CFCs and dioxin.

Administrative Civil Actions Taken Under Section 16 of TSCA Complaints Issued, Cases Completed, and Amounts Assessed (by Region)†

Region	Total No. complaints issued FY 79-81	No. complaints issued in FY 1981	Total No. cases completed FY 79-81	No. cases completed* in FY 1981	Total No. of cases pending	Total civil penalty amount assessed (in $) in FY 81	Total civil penalty amount assessed (in $) FY 79-81
I	6	1	6	3	0	20,500	30,100
II	51	36	27	20	26	265,350	340,750
III	11	3	8	3	3	30,200	45,700
IV	9	7	3	2	6	19,775	23,525
V	41	23	13	9	28	71,320	102,820
VI	40	15	27	14	12	62,600	104,960
VII	16	10	8	8	8	26,150	26,150
VIII	14	8	10	5	4	34,000	83,500
IX	11	6	6	2	5	8,000	26,300
X	6	6	0	-	6	-	-
Headquarters	1	-	0	-	1	-	-
TOTAL	206	115	108	66	99	$537,895	$783,805

†All actions taken involved alleged violations of Section 6, PCB rules.

*Includes carry-over from FY 1979 and 1980.

During FY 1981 the EPA participated in interagency programs with the General Services Administration and the Department of Energy to gain compliance with the PCB rule by Federal facilities. Led by EPA the Interagency Regulatory Liaison Group (IRLG) implemented a referral inspection program to improve interagency referral of possible violations and to coordinate better the Federal response to emergency incidents that threaten public health or the environment. In addition, the Agency worked with the Organization for Economic Cooperation and Development (OECD) to foster the international implementation of compliance monitoring programs and assure international adherence to good laboratory practices standards.

Other TSCA enforcement activities in FY 1981 included entering into contracts for inspection support, sample analysis, policy and strategy research, and training manuals and materials. Finally, EPA offered pilot cooperative enforcement agreements to five states for the support of TSCA enforcement activities.

TSCA SECTION 26(a): INDUSTRY ASSISTANCE OFFICE

The Industry Assistance Office (IAO): Section 26(a) of TSCA requires the availability of a source of technical and other nonfinancial assistance to the regulated community. The Industry Assistance Office (IAO) is the contact point for communication between that community and the Office of Toxic Substances. To assist the chemical industry's understanding of the Act's implementation requirements, IAO provides both an information telephone service and the bimonthly TSCA Chemicals-in-Progress Bulletin. In addition, IAO is directing a pilot field consultancy program that is now operating in Chicago and parts of New Jersey to assist small businesses with their premanufacture notices. This program will be evaluated for possible expansion to other areas of the country.

TSCA SECTION 28(c): STATE PROGRAMS

State programs: Section 28(c) of TSCA authorizes EPA to award grants to States for programs to prevent or eliminate problems created by toxic substances that EPA is unable or unlikely to act on under TSCA. On August 28, 1978, EPA announced in the Federal Register the availability of $3 million for this Federal assistance program and provided guidance to prospective applicants. The announcement also described a two-cycle award process; approximately half the funds were to be distributed each time.

Nine states (Arkansas, California, Illinois, Iowa, Maryland, Michigan, New Jersey, New York, and Wisconsin) applied for funds in the first cycle. In April 1979 cooperative agreements (grants requiring substantial Federal involvement) were made with Maryland, Michigan, New Jersey, New York, and Wisconsin. Ten State applications were received in the second cycle (Colorado, Connecticut, Delaware, Louisiana, Michigan, Minnesota, North Carolina, Oklahoma, Puerto Rico,* and Illinois). Including seven applications held over from the first cycle, a total of 16 State applications were considered by EPA. In February 1980 cooperative agreements were made with three states (New Jersey, North Carolina, and Puerto Rico).

On February 11, 1980, EPA announced in the Federal Register the availability of an additional $1.25 million for a third and final cycle in the program. Eleven States (Illinois--which submitted two proposals--Louisiana, Maryland, Michigan, Minnesota, New Jersey, New York, Ohio, Puerto Rico, and Tennessee) applied for funds.

In March 1981 cooperative agreements were made with four States (Illinois, Maryland, Michigan, and Ohio). Ohio decided not to proceed with its project and returned its TSCA funds.

The funds Congress appropriated for this program have been awarded. No State-cooperative-agreement projects have yet been completed.

*As defined by TSCA, "State" includes any U.S. territory or possession.

State Cooperative Agreements Program, Project Grants Awarded		Amount (in $)
Cycle 1 (April 1979)		
MARYLAND Department of Health and Mental Hygiene	Toxic substances registry	230,935
MICHIGAN Department of Natural Resources	Critical materials program	504,500
NEW JERSEY Department of Environmental Protection	Toxic substances investigation and integration unit; expand a current project monitoring volatile organic compounds in air	453,947
NEW YORK Department of Conservation	Program to identify, characterize, and plan for managing toxic substances	348,000
WISCONSIN Department of Health and Social Sciences	Study health problems related to formaldehyde vapors from mobile home construction materials	202,947
Cycle 2 (February 1980)		
NEW JERSEY Department of Environmental Protection	Study the movement, distribution, and uptake of in-place mercury; monitor emissions of selected toxic substances; assess the ecological effects of water contaminants; establish and operate a Toxic Substances Information Resource Center; conduct a field application study of in-vitro mutagenesis tests	794,053
NORTH CAROLINA Office of the Governor	Program to identify, assess, and plan to control toxic substances by profiling substances, identifying sources and level and duration of exposure, and developing a plan to control substances posing unreasonable risk	385,000

PUERTO RICO Environmental Quality Board	Develop and manage the Commonwealth's toxic substances management strategy; expand an existing public participation/awareness program	258,394
Cycle 3 (March 1981)		475,626
ILLINOIS Department of Public Health	Develop an integrated voluntary system for detecting morbidity and mortality resulting from exposure to toxic substances	
MARYLAND Department of Health and Mental Hygiene	Develop a program to assure the safe and effective containment of toxic substances in storage tanks	100,000
MICHIGAN Department of Natural Resources	Develop an interdepartmental risk assessment process	532,258

LITIGATION

Environmental Defense Fund, Inc. v. Environmental Protection Agency (No. 79-1580, D.C. Cir.). In 1979 the Environmental Defense Fund (EDF) petitioned for review of EPA's regulations under TSCA Sections 6(e)(2) and (3) governing the manufacture, processing, distribution, and use of polychlorinated biphenyls (PCBs). The petition challenged three elements of the regulation: EPA's determination that certain commercial uses of PCBs are "totally enclosed" and therefore exempt from regulation under TSCA; the limitation of applicability of the regulation to materials containing PCBs in concentrations greater than 50 parts per million (ppm); and EPA's decision to permit 11 non-totally enclosed uses of PCBs. On October 30, 1980, the Court found that there was no substantial evidence in the record to support the first two elements and remanded them to EPA for further proceedings. The third element was upheld.

The effect of this decision would have made continued use of PCB-containing transformers, capacitors, and electromagnets and the continued manufacture, processing, and use of PCBs below 50 ppm violations of Section 6(e) of TSCA. PCBs are widely used in electrical equipment and are incidentally generated in a variety of industrial processes. Because of the substantial difficulties this decision would have caused for industry, the EPA, EDF, and industry intervenors petitioned the Court to stay its mandate to permit EPA to conduct a new rulemaking. The Court issued orders on February 12, and April 13, 1981, that stayed issuance of the mandate; adopted a plan and established a schedule for EPA to conduct new rulemaking; required persons continuing to use electrical equipment with PCBs in certain concentrations to adhere to the terms of an interim inspection and reporting program; and required Edison Electric Institute (EEI), an intervenor, to conduct a study on the use of PCBs in electrical equipment and to submit the study to EPA to aid in developing the new rules. The orders established the following schedules for new rulemaking: by July 1982 EPA must promulgate a final rule on the use of PCBs in electrical equipment; by October 1982 EPA must promulgate a final rule with respect to excluding "controlled wastes" and "closed manufacturing processes" from the statutory bans; and by March 1982 EPA must advise the Court of plans for further action with respect to the regulation of other PCBs in low concentrations.

EDF has petitioned the Court under Section 19(d) of TSCA for an award of attorneys' fees. EDF's request of $156,600 was computed by (1) multiplying by the prevailing market rate for attorney's fees the time spent by EDF attorneys in preparing the case and participating in negotiations in petitioning the Court to stay its mandate, and (2) multiplying the result of the foregoing computation by an adjustment based on the difficulties in prosecuting the litigation and the quality of representation. EPA has opposed the award for lack of adequate supporting

documentation or, alternatively, argues that the award be substantially reduced from that requested by EDF.

Aluminum Company of America v. Du Bois (No. C80-1178V; W.D. Wash.). Plaintiffs sued EPA, the EPA Administrator, and the Regional Administrator for Region X for a declaratory judgment that Section 11(a) of TSCA does not authorize EPA to designate EPA contractors as EPA representatives for purposes of performing statutory inspections and for an injunction to prevent such inspections. EPA filed a motion to dismiss the complaint for lack of jurisdiction and because Section 11 clearly authorizes EPA to designate contractors as representatives for purposes of inspections.

The Court found that EPA is authorized to use non-Agency employees as contractors to conduct investigations under Section 11 of TSCA. ALCOA is appealing the decision before the Ninth Circuit.

There is nothing further to report on the following cases, which were noted in last year's report:

Olin Corporation v. EPA (No. 79-1437, 4th Cir.)

General Electric Company v. EPA (No. 79-1816, D.C. Cir.)

Aluminum Company of America v. EPA (No. 79-1811, D.C. Cir.)

Warren County v. State of North Carolina, et al. (No. 79-560-CIV-5, E.D.N.C.)

T. Mitchell Langdon et al. v. James B. Hunt et al. (No. 86-487-CIV-5, E.D.N.C.)

Dow Chemical Company v. Douglas Costle (Civ. Action No. 79-581, D. Del.)

OTHER TSCA ACTIVITIES

TSCA Section 12(b): Section 12(b) requires persons exporting or intending to export a chemical substance or mixture that has been subject to certain actions under sections 4, 5, 6, and 7 of TSCA to notify EPA. The Agency in turn must notify the importing country of the export and EPA's regulatory action. On December 16, 1980, the Agency promulgated the final Section 12(b) rule to govern submission of these notices to EPA. On July 21, 1981, EPA published a notice clarifying which exports of asbestos are subject to the notification requirements. The requirements of Section 12(b) currently apply to CFCs, PCBs, N-methanesulfonyl-p-toluene-sulfonamide, asbestos, and TCDD.

TSCA Section 13: Section 13 requires the Secretary of the Treasury to refuse entry of any chemical substance, mixture, or article into the United States if it violates TSCA or a rule under TSCA. EPA is consulting with the United States Customs Service on the development of a rule to implement Section 13. The Customs Service proposed a rule in late 1980. EPA simultaneously proposed a policy statement regarding imports under TSCA.

MAJOR PROBLEMS

Recent reviews of the Environmental Protection Agency's administrative procedures suggest that the implementation of the Toxic Substances Control Act may be adversely affecting technological innovation in the chemical industry. Such an impact may be particularly likely to occur under Section 5, premanufacture review notification for new chemicals, and under Section 4, testing of chemicals. The new Administration will be taking a hard look at the administrative procedures to see if, in fact, hinderances to innovation do exist. If a positive determination is made, the Administration will be analyzing new ways to protect health and the environment while enhancing chemical development and research. For example, in response to the Vice President's Task Force on Regulatory Reform, the Agency is seeking to identify new chemicals that do not present an unreasonable risk, so that they can be exempted from all or part of the PMN requirements.

RECOMMENDATIONS FOR ADDITIONAL LEGISLATION

No recommendations for additional legislation are determined to be necessary in FY 1982 to implement TSCA.